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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,490	06/14/2001	Roger G. Little II	11021US07 / 100-238.C3	1110

7590 10/24/2003

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/881,490	LITTLE ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication app ars on the cover sheet with the corresp ndence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *7,9,11,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6,8,10,12 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-15) is acknowledged. The traversal is on the ground(s) that the claims not be restricted because the method claims were searched and examined and issued in U.S. Patent Nos. 5,858,974 and 6,156,730. In view of this argument and a review of the above patents the method claims have been rejoined, however, the requirement for the election of the specific sequence remains.

2. Applicant telephonically elected to prosecute SEQ ID NO: 126 on September 30, 2003 without traverse. Therefore, claims 7, 9, 11, 13 and 14 are withdrawn as directed to a non elected invention.

Claim Disposition

3. Claims 1-21 are pending. Claims 1-6, 8, 10, 12 and 15-21 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-6, 8, 10 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to antifungal peptides, which reads on products of nature. In view of the absence of the hand of the inventor the claims should be amended to recite, for example, “isolated” or "purified" in connection with the peptide to identify a product not found in nature (see MPEP 2105). Note also that the claims are open ended via comprising (claim 1, line 2), thus the claim also reads on any protein or peptide containing the recited sequence.

Basis For Statutory Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-4, 6, 8, 10, 12, 13 and 15-21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 6,156,730. The patented claims and the claims in the instant application have the same language, scope, wording and subject matter. This is a double patenting rejection.

Basis For NonStatutory Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-4, 6, 8, 10, 12 and 15-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-15 of U.S. Patent No. 5,858,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to an antifungal peptide having the same core sequence. Although the length varies (six to fourteen in the patent and seven to twelve in the instant application), the two inventions are obvious variations of each other. Note that the patented claims reads on the instant claims as the range set in the instant application is encompassed within the range of the patent.

Therefore, the claims of the patent makes obvious the claimed invention in the instant application. Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions since the language in the claim is similar. Thus, the patented claims are an obvious variation of the instant application claims.

This is a obviousness-type double patenting rejection.

9. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of prior U.S. Patent No. 6,156,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to an antifungal peptide having

the same core sequence. Although applicant elected a specific sequence in the instant application the patented claims scope includes the elected sequence. Therefore, the claims of the patent makes obvious the claimed invention in the instant application. Thus, the patented claims are an obvious variation of the instant application claims.

This is a obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-6, 8, 10, 12 and 15-21 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite for the recitation of "and/or" because it is unclear if the slash mark means just "and", "or" or "and or". The dependent claims hereto are also included in this rejection.

For clarity, claims 5, 6 and 12 should recite "according to any one of claims ...." , see for example claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-6 and 15 are rejected under 35 U.S.C 102(b) as being anticipated by Van Leeuwan et al. (WO 95/10297, April 20, 1995).

Van Leeuwan et al. disclose a peptide (BPI protein, SEQ ID NO: 93) having seven to twelve amino acids, consisting of the core amino acid sequences and one or more cationic amino acids (claim 1, see the alignment and page 71 of the reference). The sequence taught by Van Leeuwan et al. also anticipates claims 2-4 because the claims recite the open language "having" which means the sequence can be longer. Claims 6 and 8 are anticipated by the Van Leeuwan et al. sequence because the sequence reported by the reference has the same structure thus consists of D-isomer. Van Leeuwan et al. disclose a pharmaceutical composition as recited in claim 15 (see page 7).

12. Claims 1-6 and 15 are rejected under 35 U.S.C 102(b) as being anticipated by Cohen et al. (WO 95/08344, March 30, 1995).

Cohen et al. disclose a peptide (BPI protein, SEQ ID NO: 92) having seven to twelve amino acids, consisting of the core amino acid sequences and one or more cationic amino acids (claim 1, see the alignment and page 170 of the reference). The sequence taught by Cohen et al. also anticipates claims 2-4 because the claims recite

the open language "having" which means the sequence can be longer. Claims 6 and 8 are anticipated by the Cohen et al. sequence because the sequence reported by the reference has the same structure thus consists of D-isomer, an inherent property. Cohen et al. disclose a pharmaceutical composition as recited in claim 15 (see page 14).

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you

choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS
Patent Examiner

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